Testimony of Ron Cohen, M.D. to the Environment, Technology, and Standards Subcommittee of the U.S. House of Representatives' Committee on Science

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Rayburn House Office Building, Room 2318

Key Points of Dr. Cohen's Testimony:

- The biotechnology industry is unique in that it takes at least several hundred million dollars and an average of 10-15 years to develop a drug from concept through to market. Biotechnology companies therefore must rely on venture investment as well as grant sources for sufficient funding.
- By imposing an unnecessary restriction against venture capital owned small business, the SBIR program is denying talented scientists the opportunity to develop new therapies and medical technologies at an early stage, to achieve sufficient proof of principle so that venture capitalists will be willing to invest in them. This exclusion is not consistent with the purpose of the SBIR program, which is to stimulate small businesses that will commercialize important technological developments.
- A prohibition against venture capital owned companies is stifling innovation by lowering the number of applicants and making the SBIR program less competitive. It also is impeding the ability of the National Institutes of Health, which provide most of the SBIR grants received by biotechnology companies, to accomplish their mission of improving the health and medical care of the American people.
- I support BIO's recommendation that the SBA adopt a rule that addresses the actual ownership structure of small biotechnology companies that are owned and controlled by venture capital companies. Specifically, change the size requirements to permit venture capital ownership of SBIR applicants to count toward the 51% U.S. ownership and control requirement.

Good Morning. My name is Dr. Ron Cohen. I am the Founder, President and CEO of Acorda Therapeutics. Acorda is a privately held biotechnology company located in Hawthorne, New York. My company's mission is to develop and market therapies that restore neurological function to people with spinal cord injury, MS and related conditions of the nervous system.

I would like to thank the members of the committee for the opportunity to comment on the current obstacles to participation in the Small Business Innovation Research (SBIR) program by businesses that are majority-owned by venture capital companies.

As you know, the biotechnology industry is unique in that it takes a large amount of capital –at least hundreds of millions of dollars – to develop a drug from concept through to market. These costs are simply too high for individuals to fund. Biotechnology companies must rely on venture investment and grant sources for sufficient funding.

Small biotechnology companies often rely on SBIR Phase I and Phase II grants to fund cutting edge research in areas that most venture capitalists would consider too early stage to fund.

However, according to the current eligibility standards, a business must be at least 51% owned and controlled by "individuals" who are citizens of the United States and the company may not have more than 500 employees, including its affiliates.

The problem facing the biotechnology industry is that the SBA's Office of Hearings and Appeals has interpreted the term "individuals" to mean human beings. There is no definition of the term "individual" in the law that established the SBIR Program. The SBA's current interpretation of "individuals" excludes venture capital companies.

This exclusion is not consistent with the purpose of the SBIR program, which is to stimulate small businesses that will commercialize important technological developments. Not only does this interpretation go against Congress' original intent for the program, but it is likely also to stifle innovation by lowering the number of applicants and making the SBIR program less competitive.

A recent survey conducted by the Biotechnology Industry Organization (BIO), of which Acorda is a member, shows that SBA's interpretation is preventing many small biotechnology companies from participating in the SBIR program. More than 70% of the companies surveyed were privately owned small businesses with fewer than 50 employees. However, many of these companies were deemed ineligible to receive a SBIR grant due to their venture capital funding. In the past five years, 62% of the survey respondents, comprising both public and private companies, had applied for SBIR grants. Half of these applicants were denied grants due to the current interpretation of the size standards.

Finally, more than 60% of the privately-held companies surveyed reported choosing not to apply for SBIR grants at all due to perceived eligibility concerns.

The results of BIO's survey illustrate the negative impact that the exclusion of VC-backed companies is having on the biotechnology industry and on medical innovation. In imposing this unnecessary restriction, the SBIR program is denying talented scientists the opportunity to develop new therapies and medical technologies at their early stages, to achieve sufficient proof of principle to attract venture capitalists to invest in their later stages of development. It also is impeding the ability of the National Institutes of Health, which provide most of the SBIR grants received by biotechnology companies, to accomplish their mission of improving the health and medical care of the American people. In the end, even the best science requires long, risky and expensive development to be translated into usable therapies, something that only companies are equipped to do effectively.

I believe Acorda exemplifies Congress' original intent with respect to the SBIR program. We currently employ 59 full-time associates, most of whom are highly educated and skilled. Acorda has received several grants through the SBIR program and these grants have been critical to our ability to develop technologies that have the potential to benefit people living with spinal cord injury and multiple sclerosis. Our lead clinical product, Fampridine-SR, is a novel therapy that is the first shown in clinical trials to improve neurological function, such as walking and strength, in people with MS. SBIR grants supported early proof of concept data for this product and helped persuade venture capitalists to support subsequent stages of development. These venture

capitalists have provided well over $140 million in investment capital to date, already providing the SBIR program with an outstanding "return" on its investment. Acorda recently has begun a large-scale, pivotal trial of Fampridine-SR in MS.

It is important to understand that even small businesses that have raised large amounts of investment capital can still put SBIR grants to productive use. Typically, such companies' invested venture capital is earmarked for the very expensive later stage projects that require tens to hundreds of millions of dollars to complete. But these same companies often have earlier stage projects, as well, that the venture capital investors are unwilling to fund. Yet, because such companies have built an infrastructure of talented professionals to develop their later stage programs, and also have developed networks of venture capital investors, they are uniquely positioned to successfully develop their earlier stage programs, as well. SBIR grants can and do provide the "proof of principle" required by these early stage projects, even within "well-funded" companies, to persuade the venture capitalists to fund subsequent stages of development.

I support BIO's recommendation that the SBA adopt a rule that addresses the actual ownership structure of small biotechnology companies that are owned and controlled by venture capital companies. Specifically, change the size requirements to permit venture capital ownership of SBIR applicants to count toward the 51% U.S. ownership and control requirement. This change would allow greater participation in the SBIR program and help to sustain important programs at small companies so they reach the point where novel therapies can enter the clinic and potentially save lives.

This change would ensure that small businesses with ownership structures similar to mine would be able to benefit from this important program and pursue research efforts that are critical to improving our nation's health, maintaining its technological leadership and advancing its economic well-being.

Thank you.